



**BILLING CODE 4510-CR-P**

**DEPARTMENT OF LABOR**

**Office of Workers' Compensation Programs**

**20 CFR Part 718**

**RIN 1240-AA12**

**Black Lung Benefits Act: Quality Standards for Medical Testing**

**AGENCY:** Office of Workers' Compensation Programs, Labor.

**ACTION:** Request for Information.

**SUMMARY:** The Black Lung Benefits Act provides benefits to miners who are totally disabled due to pneumoconiosis arising out of coal mine employment and to certain miners' survivors. Determining benefits entitlement necessarily entails evaluating the miner's physical condition, particularly his or her respiratory system. These evaluations usually involve medical tests that assess the miner's respiratory capacity. To promote accuracy when tests are conducted in connection with a claim, the program regulations set out quality standards for administering and interpreting two commonly used tests: pulmonary function tests and arterial blood gas studies. The Office of Workers' Compensation Programs (OWCP) is considering updating the quality standards, which were last amended in 2000, to better reflect current medical technology and practice. This request for information seeks the public's input on current standards for administering pulmonary function tests and arterial blood gas studies; criteria used to evaluate the results of these tests; whether OWCP should adopt quality standards for

additional testing methods; and the economic impact of any changes to the quality standards.

**DATES:** The Department invites written comments on the request for information from interested parties. Written comments must be received by **[INSERT DATE 120 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**.

**ADDRESSES:** You may submit written comments by any of the following methods. To facilitate receipt and processing of comments, OWCP encourages interested parties to submit their comments electronically.

- Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions on the Web site for submitting comments.
- Facsimile: (202) 693-1395 (this is not a toll-free number). Only comments of ten or fewer pages, including a Fax cover sheet and attachments, if any, will be accepted by Fax.
- Regular Mail/Hand Delivery/Courier: Submit comments on paper to the Division of Coal Mine Workers' Compensation Programs, Office of Workers' Compensation Programs, U.S. Department of Labor, Room C-3520, 200 Constitution Avenue, N.W., Washington, D.C. 20210. The Department's receipt of U.S. mail may be significantly delayed due to security procedures. You must take this into consideration when preparing to meet the deadline for submitting comments.

Instructions: You must include the agency name and the Regulatory Information Number (RIN) for this rulemaking in your submission. *Caution:* All comments received will be posted without change to <http://www.regulations.gov>. Please do not include any

personally identifiable or confidential business information you do not want publicly disclosed.

Docket: For access to the rulemaking docket and to read background documents or comments received, go to <http://www.regulations.gov>. Although some information (*e.g.*, copyrighted material) will not be available through the website, the entire rulemaking record, including copyrighted material, will be available for inspection at OWCP. Please contact the individual named below if you would like to inspect the record.

**FOR FURTHER INFORMATION CONTACT:** Michael Chance, Director, Division of Coal Mine Workers' Compensation, Office of Workers' Compensation Programs, U.S. Department of Labor, 200 Constitution Avenue, N.W., Suite N-3520, Washington, D.C. 20210. Telephone: 1-800-347-2502. This is a toll-free number. TTY/TDD callers may dial toll-free 1-800-877-8339 for further information.

## **SUPPLEMENTARY INFORMATION:**

### **I. Background of this Rulemaking**

The Black Lung Benefits Act (BLBA), 30 U.S.C. 901–944, provides for the payment of benefits to coal miners and certain of their dependent survivors for total disability or death due to coal workers' pneumoconiosis arising from coal mine employment. *See* 30 U.S.C. 901(a); *Usery v. Turner Elkhorn Mining Co.*, 428 U.S. 1, 5 (1976). Medical testing evidence is used to evaluate benefits entitlement in virtually every claim filed by miners and in many claims filed by survivors. For this reason, the BLBA gives the Secretary of Labor authority to develop, in consultation with the National Institute for Occupational Safety and Health (NIOSH), “criteria for all

appropriate medical tests ... which accurately reflect total disability in coal miners.” 30 U.S.C. 902(f)(1)(D).

The Department of Labor first published “Criteria for the Development of Medical Evidence,” commonly referred to as the “quality standards,” on February 29, 1980. 45 FR 13679–85; 13694–712. Originally published at 20 CFR 718.102–718.103, 718.105 and appendices A–C (1981), these standards set out detailed requirements for administering chest radiographs, pulmonary function tests (PFTs), and arterial blood gas studies (ABGs). The Department based the requirements on then-current medical industry practices, standards, and equipment. *See, e.g.*, 45 FR 13697. The quality standards were intended to ensure that claims determinations were based on the best available medical evidence.

Simultaneously, the Department adopted criteria to establish total disability based on these tests. 45 FR 13687–90, 13699–13711, 20 CFR 718.204 and appendices B–C (1981). PFT and ABG results that met the criteria in part 718, appendices B or C (commonly referred to as “qualifying” results) were sufficient, absent “contrary probative evidence,” to establish total respiratory disability. 45 FR 13688, 20 CFR 718.204(c) (1981). For PFTs, the criteria addressed the forced expiratory volume in 1 second (FEV<sub>1</sub>), the forced vital capacity (FVC), and the maximum voluntary ventilation (MVV) maneuvers.

The quality standards and the disability criteria remained the same until 2000 when, in addition to a few revisions to the existing PFT standards, the Department required that a “flow-volume loop” be included in each PFT. The Department adopted

this requirement to increase the reliability of the testing results. *See* 65 FR 79929–30 (Dec. 20, 2000), 20 CFR 718.103(a) (2001).

In the 2000 rulemaking, the Department also added two additional points related to all of the quality standards. First, the Department clarified that the standards for test administration applied only to tests conducted “in connection with a claim” for benefits after the date the regulations went into effect (*i.e.*, after January 19, 2001). 65 FR 79927–29, 20 CFR 718.101(b) (2001). Second, the Department required that any test subject to the quality standards had to be in “substantial compliance” with the applicable standard to be valid evidence. *Id.* Before then, the regulations imposed this requirement only on PFTs. *See* 20 CFR 718.103(c) (1999).

In 2014, OWCP, in consultation with NIOSH, comprehensively revised the standards applicable to chest radiographs and added new standards addressing digital imaging methods. 79 FR 21606–15 (April 17, 2014), 20 CFR 718.101 and appendix A (2015). OWCP also updated the criteria for establishing pneumoconiosis by chest radiograph. 79 FR 21612, 20 CFR 718.102 (2015).

OWCP is now considering, again in consultation with NIOSH, updating the standards for administering PFTs and ABGs and the criteria for establishing total disability based on these tests. OWCP’s goal is to adopt regulations that reflect current medical technology and practice.

## **II. Information Request**

OWCP requests input from medical professionals, medical associations, black lung clinics, miners, employers, insurance carriers, trade associations, and other interested parties on current techniques, equipment, and best practices for administering

PFTs and ABGs to ensure accurate and reliable results. OWCP also seeks input on PFT- and ABG-related criteria for establishing total respiratory disability under the BLBA. Finally, OWCP requests information regarding whether test administration standards or qualifying disability criteria should be developed for other tests (for example, pulse oximetry) and, if so, what those standards or criteria should be.

When responding, please:

- Address your comments to the topic and question number whenever possible.  
For example, you would identify your response to questions regarding administration of PFTs, Question 1, as “A.1.”
- Provide your rationale for your views.
- Provide sufficient detail in your responses to enable proper agency review and consideration. OWCP wants to fully understand your answers and any recommendations you make.
- Identify the information on which you rely. Please provide specific examples.  
Include applicable data, studies, or articles regarding standard professional practices, availability of technology, and costs.

OWCP invites comment in response to the specific questions posed below and encourages commenters to include any related cost and benefit data. OWCP is especially interested in issues related to the economic impact on small entities as defined by the Regulatory Flexibility Act, 5 U.S.C. 601(6).

Please note that as used in the questions below: (1) “administration” refers to the methods, equipment, and techniques used to conduct the test and interpret the results; and

(2) “criteria” refers to the values set to define total respiratory disability (*i.e.*, “qualifying” test results) in coal miners absent contrary probative evidence.

#### **A. Pulmonary Function Tests – Test Administration**

OWCP is considering aligning the black lung program’s PFT administration standards, currently codified at 20 CFR 718.103 and part 718, appendix B, with NIOSH’s requirements for NIOSH-approved spirometry facilities and the Social Security Administration’s (SSA’s) medical testing standards for evaluating respiratory disorders, both of which were updated in 2016. *See* 81 FR 37138–53 (June 9, 2016), 20 CFR part 404, subpart P, appendix 1, part A, Listing 3.00 *et seq.* (SSA); 81 FR 73274–77, 73286–90 (Oct. 24, 2016), 42 CFR part 37, subpart—Spirometry Testing (NIOSH). OWCP seeks information on the following issues:

1. Should OWCP require PFTs to be administered according to the procedures in pages 323–326 of M.R. Miller, et al., ATS/ERS Task Force: Standardisation of Lung Function Testing, *Standardisation of Spirometry*, 26 Eur. Respir. J. 319 (2005) (“2005 ATS/ERS Standardisation of Spirometry”), including M.R. Miller, et al., *Standardisation of Lung Function Testing: the Authors’ Replies to Readers’ Comments*, 36 Euro. Respir. J. 1496 (2010). *See* 42 CFR 37.95(c)(5). Are there alternative standards OWCP should consider?
2. Should OWCP require spirometers to undergo calibration checks according to the procedures on pages 322–323 in 2005 ATS/ERS Standardisation of Spirometry? *See* 42 CFR 37.93(b)(1). Are there alternative standards OWCP should consider?
3. Should OWCP require spirometers to meet the specifications for spirometer accuracy, precision, and real-time display size and content listed on pages 322

(Table 2), 325, and 331–333 in 2005 ATS/ERS Standardisation of Spirometry? 42 CFR 37.93(b)(2), 37.95(b). Are there alternative standards OWCP should consider?

4. Should OWCP require each person administering a spirometry test to complete NIOSH-approved training and maintain a valid NIOSH certificate by periodically completing NIOSH-approved refresher courses? *See* 42 CFR 37.95(a).
5. Currently, appendix B to part 718 provides that PFTs “shall not be performed during or soon after an acute respiratory illness.” Should OWCP further define this requirement? If so, how should it be defined?
6. Are there any other standards OWCP should consider regarding the validity of PFTs?
7. Should OWCP consider removing MVV test administration standards (and criteria) from the regulations given its limited usefulness? *See, e.g.,* R. Pellegrino, et al., ATS/ERS Task Force: Standardisation of Lung Function Testing, *Interpretive Strategies for Lung Function Tests*, 26 Eur. Respir. J. 957 (2005) (MVV “is not generally included in the set of lung function parameters needed for diagnosis or follow-up of the pulmonary abnormalities[;]” MVV “may be of some help” in upper airway obstruction and “may be of limited value in mild-to-moderate COPD”). Please explain your view.
8. What are the costs, benefits, and the technological and economic feasibility of these potential changes to PFT administration standards?

## **B. Pulmonary Function Tests – Qualifying Disability Criteria**



The current FEV<sub>1</sub> and FVC Tables in appendix B, which specify the FEV<sub>1</sub> and FVC values that qualify as totally disabling (in the absence of contrary probative evidence) for purposes of the black lung program, are based on reference values in Ronald J. Knudson, et al., *The Maximal Expiratory Flow-Volume Curve Normal Standards, Variability, and Effects of Age*, 113 Am. Rev. of Respir. Disease 587 (1976) (“Knudson 1976”). See 45 FR 13711. OWCP is considering developing new tables based on reference values in one of two more recent studies: (1) John L. Hankinson, et al., *Spirometric Reference Values from a Sample of the General U.S. Population*, 159 Am. J. of Respir. & Critical Care Med. 179 (1999) (“NHANES III”); or (2) Philip H. Quanjer, et al., *Multi-Ethnic Reference Values for Spirometry for the 3–95-Year Age Range: The Global Lung Function 2012 Equations*, 40 Eur. Respir. J. 1324 (2012) (“GLI 2012”).

9. Is either (or both) of these sets of reference values superior to the Knudson 1976 values? Why?
10. Which of these two sets of reference values is better suited to evaluating respiratory disability in coal miners? Why?
11. Are there other sets of reference values OWCP should consider?

#### **C. Arterial Blood Gas Studies – Test Administration**

12. Should OWCP require facilities administering ABG studies and analyzing samples to either have a Clinical Laboratory Improvement Amendments of 1988 (CLIA) certificate or be CLIA-exempt? See 42 CFR 493.2.
13. Should OWCP require the use of plastic syringes instead of glass syringes? If plastic syringes are used, should OWCP prohibit icing blood samples prior to

analysis? *See, e.g.,* Thomas P. Knowles, et al., *Effects of Syringe Material, Sample Storage Time, and Temperature on Blood Gases and Oxygen Saturation in Arterialized Human Blood Samples*, 51 Resp. Care 732 (2006); Gregg L. Ruppel, *Of Time and Temperature, Plastic and Glass: Specimen Handling in the Blood-Gas Laboratory*, 51 Resp. Care 717 (2006).

14. Should OWCP require that a blood sample be analyzed within a certain time period of the sample being drawn for the result to be considered valid, and if so, what should that time period be? *See id.*
15. Currently, § 718.105(b) provides that if an exercise ABG study is conducted, “blood shall be drawn during exercise.” Should OWCP allow pulse oximetry measurements ( $S_pO_2$ ) to be used in lieu of a blood draw during exercise? *See, e.g.,* 20 CFR part 404, subpart P, appendix 1, part A, Listing 3.02C (allowing chronic impairment of gas exchange to be demonstrated through ABG test or pulse oximetry results).
16. Currently, appendix C to part 718 provides that ABG tests “must not be performed during or soon after an acute respiratory or cardiac illness.” Should OWCP further define this requirement? If so, how should it be defined?
17. What are the costs, benefits, and the technological and economic feasibility of these suggested changes to ABG administration standards?

#### **D. Arterial Blood Gas Studies – Qualifying Disability Criteria**

18. Do the Tables in Appendix C need to be revised? If so, what criteria should OWCP consider and why?

#### **E. Pulse Oximetry ( $S_pO_2$ )**

19. Should OWCP adopt test administration standards for pulse oximetry? If so, what standards should OWCP consider adopting and why? *See, e.g.*, 20 CFR part 404, subpart P, appendix 1, part A, Listing 3.00H1–2.
20. Are there  $S_pO_2$  values that would establish total respiratory disability in a coal miner under the BLBA absent contrary probative evidence? If so, what values should OWCP consider and why?
21. Should OWCP require a threshold measurement of a miner's oxygen saturation level through pulse oximetry before determining whether more invasive testing such as an ABG is necessary? If so, what should the threshold be? What are the advantages and disadvantages (including potential costs or benefits) of adopting such a threshold measurement?

**F. Diffusing Capacity of the Lungs for Carbon Monoxide (DLCO)**

22. Should OWCP adopt test administration standards for DLCO testing? If so, what standards should OWCP consider adopting and why? *See, e.g.*, Brian L. Graham, et al., *2017 ERS/ATS Standards for Single-Breath Carbon Monoxide Uptake in the Lung* (2017); 20 CFR part 404, subpart P, appendix 1, part A, Listing 3.00F1–3.
23. Are there DLCO values that would establish total respiratory disability in a coal miner under the BLBA absent contrary probative evidence? If so, what values should OWCP consider and why?

**G. Other Information**

24. Please provide any other data or information that may be useful to OWCP in evaluating its quality standards and related disability criteria, including whether

there are other tests of respiratory disability for which quality standards or qualifying disability criteria should be developed.

Dated: September 18, 2019.

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[FR Doc. 2019-20851 Filed: 9/26/2019 8:45 am; Publication Date: 9/27/2019]